PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
SCB 740 PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP02/13473	26.11.2002	28.12.2001
International Patent Classification (IPC) or both national classification and IPC		
A61K9/70, A61K9/70		
Applicant		
FIDIA FARMACEUTICI S.P.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.06.2003	25.11.2003
Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Rauter, A Telephone No. +49 89 2399-8645

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP02/13473

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-4 as originally filed

Claims, Numbers

1-13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-13
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-13
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations

see separate sheet

SECTION V. .....

1. Reference is made to the following documents:

   D1: WO-A-0 045 795
   D2: WO-A-0 154 674
   D3: US-A-4 876 092
   D4: EP-A-0 848 950
   D5: EP-A-0 524 582

2. The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matters of independent claims 1 and 11 are not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

   Present formulation comprises according to independent claim 1 essentially a suspension of
   - diclofenac sodium
   - polyoxyl hydrogenated castor oil
   - a certain cationic copolymer comprising a crosslinking agent, and
   - an adhesive system.

   Claim 11 relates to a tissue patch comprising the said formulation.

   Document D1 discloses already products, *ie* a formulation and a patch which can be subsumed under such wordings. Your attention is drawn *eg* to claims 1, 5, 10, 11, 14, 15 and 17; or *eg* page 3, line 25 - page 4, line 5; page 5, line 18; page 6, line 23 - page 8, line 18, of D1; page 9, lines 24 - 26.

   Further novelty destroying disclosure can be taken from *eg*
   D2: See *eg* the claims; example 15.

   Further pertinent prior art is disclosed in D3 - D5, particularly with respect to the use of diclofenac sodium in polyoxyl hydrogenated castor oil.

   Dependent claims do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step; presently defined embodiments can either be taken *expressis verbis* from either D1 or D2, or must be considered obvious

for the person skilled in the art from the teachings of D3 - D5.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.